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Pharmaceutical Products, Inc. and  
6 Abbott Laboratories

7 UNITED STATES DISTRICT COURT  
8 FOR THE DISTRICT OF NEVADA  
9

10 KARIN KLEIN,

Plaintiff,

CASE: 2:08-cv-00681-RLH-RJJ

11 vs.

12 TAP PHARMACEUTICAL PRODUCTS,  
13 INC.; ABBOTT LABORATORIES; TAKEDA  
14 CHEMICAL INDUSTRIES, LTD., and DOES  
I through V, inclusive,

Defendants.

**DEFENDANT ABBOTT  
LABORATORIES' ANSWER TO  
COMPLAINT**

**(Jury Demanded)**

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16  
17 Defendant Abbott Laboratories ("Abbott"), by its undersigned counsel, hereby answers  
18 plaintiff's complaint as follows:

19 **GENERAL ALLEGATIONS**

20  
21 1. Abbott lacks knowledge and information sufficient to form a belief about the truth  
22 of the allegations in paragraph 1, and thus denies them.

23 2. In response to paragraph 2, Abbott admits that TAP Pharmaceutical Products Inc. is  
24 a Delaware corporation, has conducted business in the state of Nevada, and has manufactured and  
25 sold the pharmaceutical known as Lupron. Abbott denies any remaining allegations in paragraph  
26 2.  
27  
28

1           3.       In response to paragraph 3, Abbott admits that Abbott Laboratories is an Illinois  
2 corporation and that it has conducted some business in Clark County, Nevada. Abbott denies the  
3 remaining allegations of paragraph 3.

4           4.       In response to paragraph 4, Abbott admits that Takeda Chemical Industries, Ltd.  
5 was a Japanese corporation. Abbott denies the remaining allegations of paragraph 4.  
6

7           5.       In response to paragraph 5, Abbott denies all allegations applicable to TAP  
8 Pharmaceutical Products Inc., Abbott Laboratories, and Takeda Chemical Industries, Ltd. Abbott  
9 lacks knowledge and information sufficient to form a belief about the truth of the allegations  
10 pertaining to the unknown entities, and therefore denies them.

11           6.       In response to paragraph 6, Abbott admits that TAP Pharmaceutical Products Inc.  
12 has marketed, produced, sold and distributed Lupron. Abbott denies the allegations as to the other  
13 named defendants and any remaining allegations in paragraph 6.  
14

15           7.       Abbott lacks knowledge and information sufficient to form a belief about the truth  
16 of the allegations in paragraph 7, and thus denies them.

17           8.       Abbott denies each and every allegation contained in paragraph 8.

18                               **FIRST CAUSE OF ACTION**

19                               **(STRICT LIABILITY)**

20  
21           9.       In response to paragraph 9, Abbott repeats and incorporates its answers to the  
22 allegations contained in paragraphs 1 through 8 as though fully set forth.

23           10.       Abbott denies each and every allegation contained in paragraph 10.

24           11.       Abbott denies each and every allegation contained in paragraph 11.

25           12.       Abbott denies each and every allegation contained in paragraph 12.

26           13.       Abbott denies each and every allegation contained in paragraph 13.  
27  
28

**SECOND CAUSE OF ACTION**

**(NEGLIGENCE)**

14. In response to paragraph 14, Abbott repeats and incorporates its answers to the allegations contained in paragraphs 1 through 13 as though fully set forth.

15. Abbott denies each and every allegation contained in paragraph 15.

16. Abbott denies each and every allegation contained in paragraph 16.

17. Abbott denies each and every allegation contained in paragraph 17.

18. Abbott denies each and every allegation contained in paragraph 18.

**THIRD CAUSE OF ACTION**

**(BREACH OF WARRANTY)**

19. In response to paragraph 19, Abbott repeats and incorporates its answers to the allegations contained in paragraphs 1 through 18 as though fully set forth.

20. In response to paragraph 20, Abbott admits that Lupron is and has been fit for the purposes for which it is intended. Abbott denies the remaining allegations in paragraph 20.

21. Abbott lacks knowledge and information sufficient to form a belief about the truth of the plaintiff's alleged use of the product and thus denies the first sentence of paragraph 21. Abbott denies the remaining allegations of paragraph 21.

22. Abbott denies each and every allegation contained in paragraph 22.

23. Abbott denies each and every allegation contained in paragraph 23.

24. Abbott denies each and every allegation contained in paragraph 24.

25. Abbott denies each and every allegation contained in paragraph 25.

**FOURTH CAUSE OF ACTION**

**(PUNITIVE DAMAGES)**

26. In response to paragraph 26, Abbott repeats and incorporates its answers to the allegations contained in paragraphs 1 through 25 as though fully set forth.

27. Abbott denies each and every allegation contained in paragraph 27.

## **AFFIRMATIVE DEFENSES**

Plaintiff's complaint fails to state a claim upon which relief can be granted.

The claims asserted by plaintiff are barred by the applicable statute or statutes of limitation.

If the plaintiff sustained injuries or incurred expenses, they were caused in whole or part by the acts and omissions of the plaintiff or others for whose conduct Abbott is not responsible and whose conduct Abbott had no reason to anticipate.

Lupron is a prescription medical product. The federal government has preempted the field of law applicable to the design, testing, manufacturing, labeling, warning, and marketing of prescription medical products. The design, testing, manufacturing, labeling, warning, and marketing of Lupron was at all times in compliance with applicable federal law. Plaintiff's causes of action against Abbott, therefore, fail to state a claim upon which relief can be granted; such claims, if allowed, would conflict with applicable federal law and violate the Supremacy Clause of the United States Constitution.

The methods, standards, and techniques utilized in marketing the product in question and in issuing warnings and instructions with respect to its use conformed with the generally

1 recognized, reasonably available and reliable state of knowledge at the time the product was  
2 manufactured.

3  
4 **SIXTH DEFENSE**

5 To the extent plaintiff asserts that Abbott failed to provide an adequate warning to plaintiff  
6 regarding the use of the prescription drug Lupron, Abbott asserts that any obligation to warn  
7 plaintiff was discharged through the provision of an adequate warning to plaintiff's treating and  
8 prescribing physicians.

9  
10 **SEVENTH DEFENSE**

11 Plaintiff's alleged injuries and plaintiff's damages, if any, proximately resulted from the  
12 modification, alteration, misuse, abuse, unintended and/or unforeseeable use of Lupron and  
13 consequently no act or omission on the part of Abbott proximately caused any of plaintiff's  
14 claimed injury or damage.

15  
16 **EIGHTH DEFENSE**

17 The injuries or the expenses alleged by plaintiff may have been caused, in whole or in part,  
18 by an idiosyncratic reaction, operation of nature or act of God, or by pre-existing and/or unrelated  
19 medical, genetic, and/or environmental conditions, diseases or illnesses of plaintiff.

20  
21 **NINTH DEFENSE**

22 The injuries and damages claimed by plaintiff, if any, resulted from an intervening cause or  
23 causes, and any action on the part of Abbott was not the proximate or competent producing cause  
24 of plaintiff's alleged injuries.

25  
26 **TENTH DEFENSE**

27 Plaintiff's claims against Abbott may be barred by the doctrine of laches, waiver and  
28 estoppel.

**ELEVENTH DEFENSE**

Plaintiff may have failed to join identifiable and indispensable parties necessary for proper adjudication.

**TWELFTH DEFENSE**

Plaintiff's claims against Abbott may be barred because plaintiff knowingly and voluntarily assumed the risk of injury.

**THIRTEENTH DEFENSE**

Lupron is a prescription medical product that falls within the "comment k" and "comment j" exceptions to strict liability, as defined in Restatement (Second) of Torts, § 402A. Lupron is therefore neither defective nor unreasonably dangerous when properly prepared and accompanied by proper warnings and instructions for use. At all times material to the complaint, Lupron was properly prepared and accompanied by proper warnings and instructions for use.

**FOURTEENTH DEFENSE**

The complaint is barred by the learned intermediary doctrine and the bulk seller/sophisticated user doctrine.

**FIFTEENTH DEFENSE**

At the time Lupron left TAP Pharmaceutical Products Inc.'s control, a practical and technically feasible alternative design for Lupron that would have prevented the alleged harm was not available without impairing the usefulness or intended purpose of the product, and TAP Pharmaceutical Products Inc. did not act unreasonably in introducing Lupron into the market.

**SIXTEENTH DEFENSE**

Plaintiff's claims may be barred, in whole or in part, by her failure to mitigate damages, if any.

**SEVENTEENTH DEFENSE**

Abbott is entitled to the benefit of all defenses and presumptions that may arise because Lupron conformed in all respects with the state of the art and the prevailing standards of the industry.

**EIGHTEENTH DEFENSE**

Plaintiff's complaint is barred by the applicable forum non conveniens doctrine.

**NINETEENTH DEFENSE**

Plaintiff's claims are barred by lack of privity with Abbott.

**TWENTIETH DEFENSE**

When the subject product was designed, manufactured and distributed it conformed to the state of the art and were reasonably safe, and their benefits exceed any associated risks.

**TWENTY-FIRST DEFENSE**

The product of which plaintiff complains has certain unavoidable, inherent characteristics which cannot be obviated under the state of scientific knowledge existing at the time such products were manufactured. While denying that such characteristics are dangerous or defective, if plaintiff sustained any injuries as a result of using or exposure to the product at issue, those injuries were the result of properties necessarily associated with the product that were unavoidable and for which Abbott cannot be held responsible.

**TWENTY- SECOND DEFENSE**

Plaintiff misused the product described, knowing that such misuse was unforeseen and unforeseeable to Abbott; with full knowledge of any danger resulting from misuse. Such actions legally caused and contributed to the injuries and damages, if any, plaintiff claims.

**TWENTY-THIRD DEFENSE**

Plaintiff's injuries and/or damages of the plaintiff, if any, were the result of unavoidable circumstances which could not have been prevented by anyone.

**TWENTY-FOURTH DEFENSE**

Plaintiff's exposure, if any, to products for which Abbott may be legally responsible was de minimus, so that Abbott's products, if any, were not a substantial contributing factor to any condition for plaintiff seeks recovery in this action.

**TWENTY-FIFTH DEFENSE**

The public interest and benefit in the availability of such product that is the subject matter of this action preclude liability for any risks, if any resulting from such activities, which were unavoidable given the state of human knowledge at the time those activities were undertaken. With respect to plaintiff's claims, if it determined that there is a risk inherent in the said product, then such risk, if any, is outweighed by the benefit of the product.

**TWENTY-SIXTH DEFENSE**

To the extent any entity or person, including but not limited to plaintiff, contributed to plaintiff's alleged damages and was at fault in doing so, then Abbott requests that all fault be apportioned according to the percentage of fault. Abbott further states that it expressly reserves the right, in the event that plaintiff settles with other defendants, to seek a set-off/credit for any proximal negligence that may be attributed to said settling defendant. If the jury agrees with plaintiff's position, Abbott requests that fault be allocated to the settling defendant. Abbott intends to rely, in part, on the witnesses and evidence produced by others, including witnesses retained by plaintiff. Abbott reserves the right to read portions of the depositions and use evidence necessary regarding allocation of fault even if other defendants settle before trial.



**TWENTY-SEVENTH DEFENSE**

Plaintiff's losses, if any, are subject to an off-set in the amount of any reimbursement received by plaintiff as a result of any insurance or other health benefit plan, or any amounts paid for by any insurance of other health benefits plan.

**TWENTY-EIGHTH DEFENSE**

Abbott incorporates all those defenses under the Nevada product liability law, including, but not limited to, industry custom, technological feasibility, and compliance with standards and regulations.

**TWENTY-NINTH DEFENSE**

Abbott denies any misrepresentation and/or fraud on its part, and/or reliance by plaintiff and detriment to plaintiff allegedly resulting therefrom.

**THIRTIETH DEFENSE**

Abbott denies that it is liable for actionable negligence and denies that plaintiff was injured thereby.

**THIRTY-FIRST DEFENSE**

Abbott expressly reserves the right to raise an affirmative defense that plaintiff has failed to join all parties necessary for a just adjudication of this action, should discovery reveal the existence of fact to support such a defense.

**THIRTY-SECOND DEFENSE**

Abbott hereby gives notice that it intends to rely on such other affirmative defenses as may become available or apparent during the course of discovery and reserves the right to amend its answer to assert any such defense.

**THIRTY-THIRD DEFENSE**

Abbott did not manufacture, market, sell or distribute Lupron during the relevant time period.

**JURY DEMAND**

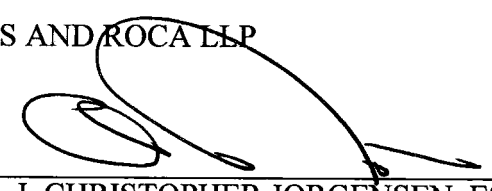
Abbott demands a trial by jury.

WHEREFORE, defendant Abbott Laboratories prays for judgment in its favor and against plaintiff, for its costs, and for such other relief as this Court deems just and proper.

DATED this 5 day of June, 2008.

LEWIS AND ROCA LLP

By

  
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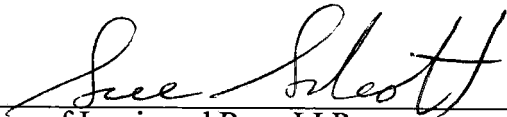
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**CERTIFICATE OF SERVICE**

I hereby certify that service of the foregoing document was made on the 5 day of June, 2008, by depositing a copy for mailing, first class mail, postage prepaid, at Las Vegas, Nevada, to the following:

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